



1645
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECONSIDERATION OF HOLDING OF ABANDONMENT UNDER MPEP §711.03 – NO ABANDONMENT IN FACT	Application #	09/982,992
	Confirmation #	7767
	Filing Date	22 October 2001
	First Inventor	PATTI et al.
	Art Unit	1645
	Examiner	Hines
	Docket #	P06922US02/BAS

Commissioner for Patents
Washington, D. C.

S I R:

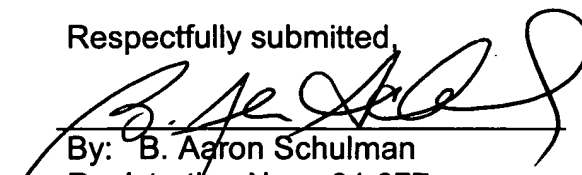
A Notice of Abandonment for the above-identified application was mailed on October 6, 2004 which indicated that this application was abandoned by failure to respond to the Office Action mailed March 24, 2002. However, a response to the Office Action was timely filed on September 24, 2004. Therefore, there was no abandonment in fact and the Notice of Abandonment was evidently mailed in error.

Enclosed herewith is a copy of the response timely filed on September 24, 2004, together with a copy of the stamped receipt for this response showing timely filing.

In view of the fact that there was no abandonment in fact, reconsideration of the holding of abandonment pursuant to MPEP §711.03 is requested. If any other action is required by Applicant to effect further prosecution, please contact the undersigned as soon as possible.

Respectfully submitted,

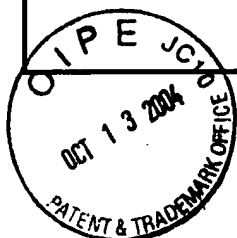
Date: 10.13.04


By: B. Aaron Schulman
Registration No.: 31,877

STITES & HARBISON PLLC ♦ 1199 North Fairfax St. ♦ Suite 900 ♦ Alexandria, VA 22314
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**PTO
STAMPED RECEIPT**

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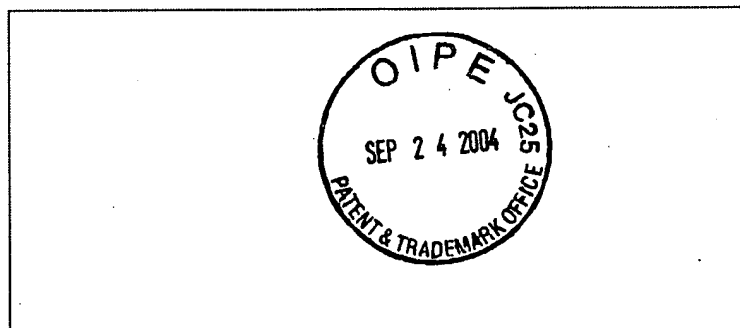
PAPERS SUBMITTED

COPY

- ☒ Transmittal Form
- ☒ Amendment/Response
 - ☒ with Attachments
 - Amendment/Response After Final
 - with Attachments
- ☒ Petition for Extension of Time
- Response to Missing Parts
- Declaration
- Translation of Application
- Assignment
- Priority Document
- ☒ Fee: \$475.00 (CREDIT CARD - PTO-2038).

- IDS: Including
 - List of References
 - Search Report
 - Statement of Relevance
 - Refs. Transmitted
 - Issue Fee Transmittal
 - Publication Fee Transmittal
 - Letter to Draftsman
 - _ sheets of formal drawings (figs.)
 - PCT Demand Chapter II
 - Notice of Appeal
 - Appeal Brief (in triplicate)

PTO Receipt Stamp →



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Customized PTO/SB/21 (04-04)

TRANSMITTAL FORM

(for all correspondence after initial filing)

Total number of pages in this submission =

Application #	09/982,992
Confirmation #	7767
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ENCLOSURES (check all that apply)

- ☒ Fees calculated below
☒ Amendment/Reply
☒ including Attachment(s)
After Final Amendment/Reply
including Attachment(s)
☒ Extension of Time Petition

- ☐ Response to Missing Parts/Incomplete Appl.
☐ Certified Copy of Priority Document(s)
☐ Information Disclosure Statement
☐ Drawing(s)
☐ Terminal Disclaimer

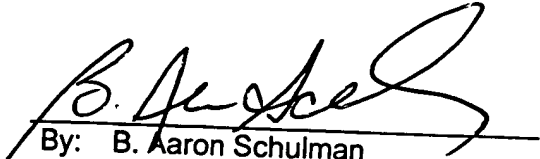
COPY**FEES CALCULATION:** For claims if required and/or other fees as shown below:

Required and/or other fees as shown below:					\$
	NOW	Previously Paid For	Present Extra	Rate	
..... TOTAL CLAIMS	28	29	0	X \$ 18 =	
..... INDEP. CLAIMS	6	6	0	X \$ 86 =	
TOTAL OF ABOVE CLAIMS FEES =					
<input checked="" type="checkbox"/> Reduction by ½ for small entity status of applicant					
SUBTOTAL =					
<input checked="" type="checkbox"/> Fee for extension of time (per attached Petition)					
..... Other fee for					475.00
TOTAL OF ALL FEES =					\$475.00

☒ A CREDIT CARD PAYMENT FORM (PTO-2038) in the amount of \$ 475.00 is enclosed.

☒ The Commissioner is authorized to charge any fee, additional fee or extension fee due in connection herewith to Deposit Account No. 12-0555:
(1) if no payment or an insufficient payment is enclosed and a fee is due in connection herewith; or
(2) if no petition for extension of time is enclosed but an EOT is required - and in this event, applicant hereby petitions under 37 CFR 1.136(a) for an extension of time of as many months as are required to render this submission timely.

Date: 24 September 2004


By: B. Aaron Schulman
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Customized PTO/SB/22 (06-04)

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)	Application #	09/982,992
	Confirmation #	7767
	Filing Date	22 October 2001
	First Inventor	PATTI et al.
	Art Unit	1645
	Examiner	Hines
	Docket #	P06922US02/BAS

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee under 37 CFR 1.17(a) are as follows.

☒ NOTE: Applicant claims small entity status.

COPY

No extension of time previously obtained. <u>Extension requested:</u>		
	<u>Large Entity Fee</u>	<u>Small Entity Fee</u>
..... One month \$ 110 \$ 55
..... Two months \$ 420 \$ 210
<input checked="" type="checkbox"/> Three months \$ 950	<input checked="" type="checkbox"/> \$ 475
..... Four months \$ 1480 \$ 740
..... Five months \$ 2010 \$ 1005

☒ A CREDIT CARD PAYMENT FORM (PTO-2038) in the amount of \$ 475.00 is enclosed.

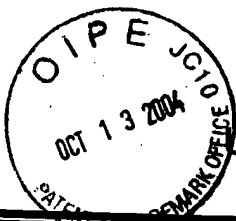
☒ The Commissioner is authorized to charge any fee or additional fee due in connection herewith to Deposit Account No. 12-0555:
(1) if no payment or an insufficient payment is enclosed and a fee is due in connection herewith; or
(2) if a further fee and petition for extension of time are required at this time - and in this event, applicant hereby petitions under 37 CFR 1.136(a) for any further extension of time of as many months as are required to render this submission timely.

Date: 24 September 2004

Signed By 
(Attorney of Record) Name: B. Aaron Schulman
Registration No.: 31,877

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UNITED STATES PATENT AND TRADEMARK OFFICE
Credit Card Payment Form

Credit Card Information

Credit Card Type:	American Express
Credit Card Account Number:	009
Credit Card Expiration Date:	12/09
Name on Credit Card:	L&T US PTO FEES
Payment Amount:	\$475.00
Cardholder Signature:	Date: 24 September 2004

Refund Policy: The Office may refund a fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee will not entitle a party to a refund of such fee. The office will not refund amounts of \$25 or less unless a refund is specifically requested, and will not notify the payor of such amounts (37 CFR § 1.26) Refund of a fee paid by credit card will be issued as accredit to the credit card account to which the fee was charged.

Service Charge: There is a \$50 service charge for processing each payment refused *including a check returned "unpaid" or charged back by a financial institution (37 CFR 1.21(m))

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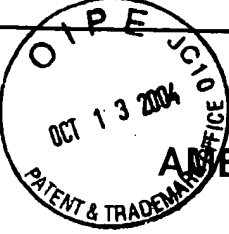
STITES & HARBISON PLLC (formerly LARSON & TAYLOR, PLC)		
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Alexandria, VA 22314		
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TEL: 703-739-4900	FAX: 703-739-9577	EMAIL: iplaw@larsontaylor.com

Request and Payment Information

Description of Request and Payment Information: \$475.00 – Three Month Extension of Time (small)

X Patent Fee	<input type="checkbox"/> Patent Maintenance Fee	<input type="checkbox"/> Trademark Fee
Appln. No.: 09/982,992	Patent No.:	Appln. No.:
Confirmation No.: 7767	Appln. No.:	Regis. No.:
Attorney Docket No.: P06922US02/BAS/1507LT-5090		Mark:

If the cardholder includes a credit card number on any form or document other than the Credit Card Payment Form, the US Patent and Trademark Office will not be liable in the event that the credit card number becomes public knowledge.

 AMENDMENT	Application #	09/982,992
	Confirmation #	7767
	Filing Date	22 October 2001
	First Inventor	PATTI et al.
	Art Unit	1645
	Examiner	Hines, Jana A
	Docket #	P06922US02/BAS

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COPY

S I R:

In response to the Official Action dated March 24, 2004, please amend the above identified application as follows.

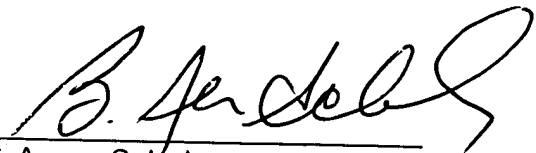
Amendments to the Claims are reflected in the listing of the claims provided herewith in **Attachment A**.

Remarks to this Amendment are provided herewith in **Attachment B**.

Excerpts from the **Revised Interim Written Description Guidelines Training Materials** are provided in **Appendix 1**.

Reconsideration and allowance of the present application is sought for the reasons as stated in the attached Remarks.

Respectfully submitted,
STITES & HARBISON, PLLC



B. Aaron Schulman
Registration No. 31,877

September 24, 2004

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ATTACHMENT A

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Amendment to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) An isolated antibody capable of binding ~~which binds~~ to the Map10 protein from *S. Staphylococcus aureus*.
2. (Original) An antibody according to Claim 1, wherein said antibody prevents *S. aureus* infection in a human or animal.
3. (Original) An antibody according to Claim 1, wherein said antibody inhibits binding of staphylococcal bacteria to eukaryotic cells.
4. (Original) An antibody according to Claim 1, wherein said antibody is suitable for parenteral, oral, intranasal, subcutaneous, aerosolized or intravenous administration in a human or animal.
5. (Original) An antibody according to Claim 1 wherein the antibody is a monoclonal antibody.
6. (Original) An antibody according to Claim 5 wherein the monoclonal antibody is of a type selected from the group consisting of chimeric, humanized and human monoclonal antibodies.

7. (Original) An antibody according to Claim 5 wherein the antibody is a single chain monoclonal antibody.
8. (Original) An antibody according to Claim 1 which comprises a antibody fragment having the same binding specificity of an antibody which binds to the *S. aureus* MAP protein.
9. (Original) An antibody according to Claim 1 having a variable light sequence according to SEQ ID NO:4.
10. (Original) An antibody according to Claim 1 having a variable light sequence encoded by a nucleic acid sequence according to SEQ ID NO:3 or degenerates thereof.
11. (Original) An antibody according to Claim 1 having a variable heavy sequence according to SEQ ID NO:6.
12. (Original) An antibody according to Claim 1 having a variable light sequence encoded by a nucleic acid sequence according to SEQ ID NO:5 or degenerates thereof.
13. (Original) An antibody according to Claim 1 wherein the antibody is a polyclonal antibody.
14. (Original) Isolated antisera containing an antibody according to Claim 1.

15. (Withdrawn) A diagnostic kit comprising an antibody according to Claim 1 and means for detecting binding by that antibody.
16. (Withdrawn) A diagnostic kit according to Claim 15 wherein said means for detecting binding comprises a detectable label that is linked to said antibody.
17. (Withdrawn) A method of diagnosing an infection of *S. aureus* comprising adding an antibody according to Claim 1 to a sample suspected of being infected with *S. aureus*, and determining if antibodies have bound to the sample.
18. (Original) A pharmaceutical composition for treating or preventing an infection of *S. aureus* comprising an effective amount of the antibody of Claim 1 and a pharmaceutically acceptable vehicle, carrier or excipient.
19. (Withdrawn) A method of treating or preventing an infection of *S. aureus* comprising administering to a human or animal patient an effective amount of an antibody according to Claim 1.
20. (Withdrawn) A method of inducing an immunological response comprising administering to a human or animal an isolated *S. aureus* Map10 protein.

21. (Withdrawn) A method of identifying antibodies to the Map10 protein comprising adding an isolated Map10 protein to a sample suspected of containing anti-MAP antibodies, and determining if antibodies have bound to the added Map10 protein.
22. (Canceled).
23. (Original) An isolated antibody according to Claim 1 that has the ability to bind to the amino acid sequence of SEQ ID NO:2.
24. (Original) An isolated antibody according to Claim 1 that has the ability to bind to an amino acid sequence coded by the nucleic acid sequence of SEQ ID NO:1 or degenerates thereof.
25. (Original) An isolated antibody having a variable light sequence according to SEQ ID NO:4.
26. (Original) An isolated antibody having a variable heavy sequence according to SEQ ID NO:6.
27. (Withdrawn) An isolated *S. aureus* Map10 protein.
28. (Withdrawn) An isolated protein according to Claim 27 having an amino acid sequence according to SEQ ID NO:2.

29. (Withdrawn) An isolated protein according to Claim 27 having an amino acid sequence encoded by a nucleic acid sequence according to SEQ ID NO:1 or degenerates thereof.

ATTACHMENT B

COPY

REMARKS

By this amendment, Applicants have amended the claims in a manner which makes it clear that the claims are proper under the applicable USPTO guidelines concerning written description, and that the Examiner's rejection on the basis of this provision is without merit. In addition, other minor objections are also overcome without affecting the scope of the claims. As will be set forth below, under the applicable guidelines and legal principals, the present set of claims is clearly in compliance with Section 112, and in light of the fact that the present claimed antibody is clearly not disclosed or suggested in the prior art, the present application is in condition for immediate allowance.

In the Official Action, the Examiner rejected Claims 1-4 under 35 U.S.C. §102(b) as anticipated by the Hook et al. patent, US 5,648,240. In particular, although the Examiner recognized that the Hook '240 patent did not disclose or suggest the specific MAP10 protein of the present invention, much less antibodies that were capable of specifically binding with this protein, the Examiner argues that the '240 patent discloses isolated antibodies to the complete MAP protein which would inherently bind to the Map10 protein. In addition, the Examiner has stated that Applicants "are not asserting that the antibody of Hook et al. and [the present] antibody are different" and that "Applicants arguments are not that the antibodies of Hook are not capable of preventing infection and suitable for administration." However, contrary to the Examiner's assertions, and as Applicants have argued, it is indeed the case that the present antibody and the antibody disclosed in the Hook '240 patent are different, that the

antibody as disclosed in Hook would **not** "inherently bind" to the Map10 antigen of the present invention, and that the antibodies as disclosed in the Hook '240 patent have **not** been shown to be useful in treating infection, unlike the present antibodies which indeed give surprising and unexpected results in terms of treating infection. Accordingly, the present claimed antibody is different from the antibodies of the prior art and is not disclosed or suggested in the Hook reference.

Moreover, it is in fact the case that antibodies raised to a complete protein are normally quite different from antibodies raised against a very small and specific subregion of that protein for a variety of reasons. In particular, the complete protein usually has folds and other physical features which prevent many of the surface epitopes from generating antibodies at all, particularly if the particular site is only a small fraction of the entire protein. In addition, there may be other interference from blocking epitopes on other sites of the protein. As a result, it is more normally the case that an antibody directed to a specific subregion is patentable over an antibody generated against the whole protein, particularly when it can be shown that the antibody to the subregion has the ability to protect against infection in a manner not shown with the antibodies to the whole protein. See, e.g., U.S. Pat. No. 6,288,214 (Antibody to M55 subregion of the CNA protein patentable over prior art antibodies to the whole CNA protein).

The present case is a similar situation to the one in U.S. Pat. No. 6,288,214 In that the Map10 protein is a very small part of the entire MHC II analog protein, only about one-seventh of the size of the whole protein, and that the Map10 protein generates antibodies which are very different from those produced from the whole

protein. In particular, as reflected in the present specification, antibodies generated from the Map10 protein were capable of treating infection, and this is something which is not shown with regard to the antibodies in the Hook '240 patent. Accordingly, it is clear that the antibodies of the present invention are quite different than the antibodies disclosed in the Hook '240 patent, and contrary to the assertions of the Examiner, the present antibodies allow for treatment of infection in a manner not heretofore possible using the antibodies of the MHC II analog protein as disclosed in the Hook patent. It is thus the case that the present antibody is clearly not disclosed or suggested in the prior Hook patent and indeed gives significantly improved results with regard to treatment of infection in a manner not shown in the Hook patent. Accordingly, the present claims are clearly not disclosed or suggested in the Hook patent, and the Examiner's rejection on the basis of this reference is respectfully traversed and should be withdrawn.

In the Official Action, the Examiner rejected Claims 1-14, 18 and 23-28 under 35 U.S.C. §112 as failing to comply with the written description requirement. In addition to citing a number of cases which do not support the Examiner's position, the Examiner cites to the "Interim Written Description Guidelines" published June 15, 1998 in the Federal Register as supporting a rejection in this case. Unfortunately, the Examiner did not refer to the current "Revised Interim Written Description Guidelines" which are available on the USPTO's own web site, and which cover the present situation exactly and show that the Examiner's rejection is wholly without merit and contradicts the current guidelines with regards to antibodies.

In particular, a copy of the relevant pages from the current Written Description Guidelines (Example 16: Antibodies, pages 59-60, attached hereto as Appendix 1)

covers the present situation exactly, and indeed the present claim language is identical to the language of the version considered as adequate under the written description requirement. In short, the "Example specification" provided in the USPTO Guidelines discloses (1) the isolation of antigen X and that it is useful for a particular purpose such as detection of infection; (2) obtaining the purified antigen and provides a clear protocol by which the antigen was isolated and (3) **"contemplates but does not teach in an example antibodies which specifically bind to antigen X"** (emphasis added). Following the Example specification, the proposed claim is as follows:

"An isolated antibody capable of binding to antigen X"

In the Example specification, the conclusion, based on the level of skill and knowledge in the art of antibodies is that:

"The disclosure meets the requirements under 35 U.S.C. §112 first paragraph as providing an adequate written description of the claimed invention"
(emphasis added)

In the present case, Applicants specification discloses (1) the isolation of the Map10 antigen and that it is useful for a particular purpose such as detection of infection; (2) obtaining the purified antigen by providing a clear protocol by which the Map10 antigen was isolated and (3) **actually teaches several antibodies which were produced and which specifically bind to the Map10 protein.** In other words,

Applicants specification goes **beyond** the Example specification which the US Patent Office Guidelines indicates satisfies the written description requirement, and actually discloses the production of the specific antibodies of the claims which would not have even been required to satisfy the Written Description requirement as per the guidelines. Accordingly, Applicants present Claim 1 which is directed to an isolated antibody capable of binding the Map10 antigen is **precisely** the type of claim that the Written Description Guidelines of the US Patent Office indicates has an adequate written description based on the specification. See also Enzo Biochem Inc. v. Gen-Probe Inc., 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002) (quoting the guidelines as showing that "the PTO would find compliance with § 112, for a claim to an 'isolated antibody capable of binding to antigen X'".)

Accordingly, the Examiner's rejection on the basis of the written description requirement under 35 U.S.C. §112 is respectfully traversed and should be withdrawn as totally opposite to the law and the Patent Office's own Written Description Guidelines.

In the Official Action, the Examiner rejected Claims 1-14, 18 and 23-28 under 35 U.S.C. §112 as failing to comply with the enablement requirement. In short, the Examiner argues that it would take undue or "extensive" experimentation to make and use the present invention. However, in light of the fact that one skilled in the art would not have any problems in making and using the present invention, particularly in light of the USPTO's comments in the Written Description Requirement above regarding the state of knowledge when it comes to antibodies, and in light of the decision in "In re Wands" discussed below, it is clear that there is no grounds for a rejection on the basis

of "undue experimentation", and that the Examiner's rejection is without merit and should be withdrawn.

In the first place, as indicated in the attached Appendix 1, the Patent Office states that with regard to the skill in the art concerning antibodies:

"The level and skill in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

* * *

"Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X."

Clearly, in light of the Patent Office's **own guidelines** regarding the **level of skill in the antibody art**, it is clearly improper for the Examiner to argue that one of ordinary skill in this art could not make or use the present invention which is simply an antibody capable of binding to Map10. The Examiner's assertions regarding modifications to proteins is somewhat irrelevant since in the first place, the skilled artisan will clearly be able to make and use the present invention, i.e., produce the claimed antibodies from the well known and well defined Map10 antigen, and secondly, no matter what

modifications are made to proteins, the bottom line is that the determination of whether a particular antibody is capable of binding to Map10 is well within the routine skill of the ordinary artisan, and thus does not present any "undue experimentation" problems for the skilled artisan.

Moreover, with regard to whether there is "undue experimentation" present so as to support a rejection under the enablement provision of Section 112, the one case which is the standard by which an enablement rejection must be assessed is the Federal Circuit decision of In re Wands which established the criteria for a determination of whether a claim is objectionable on the basis of undue experimentation. It is not surprising that the Examiner **did not** refer to the Wands case in the Official Action, since if the Examiner had referred to this case, it would have shown that this is simply **not** a case of "undue experimentation" as defined in Wands. In particular, the case of in re Wands, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988) was a case dealing with monoclonal antibodies used in an immunoassay, and the original Examiner and the Patent Board of Appeals had claimed there was "undue experimentation" because some screening was necessary to obtain the high-binding monoclonal antibodies in accordance with the claims. In the examples disclosed in the specification, out of an original 143 hybridomas prepared in accordance with the invention, only 9 were deemed suitable for further analysis, and only 4 of these were shown to have the high binding affinity needed for the antibodies of the claims.

However, despite the fact that multiple experiments were necessary to obtain antibodies which met the requirements of the claims, and despite the fact that the experiments led to many attempts which did not result in the claimed antibodies, the

Federal Circuit **reversed** the Examiner and the Board and held that the claims were in fact enabled because there was reasonable guidance provided in the application, and because any necessary experimentation was simply **routine** one of ordinary skill in the art. In particular, the Federal Circuit held that the test for "undue experimentation" was not merely quantitative, but instead was based on whether any experimentation needed was **routine**. As the Court stated, "the test is not merely quantitative, since a considerable amount of experimentation is permitted, **if it merely routine**, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." 8 U.S.P.Q.2d at 1404 (emphasis added). Accordingly, the Federal Circuit held that there was **no** "undue experimentation" necessary to make and use the invention because the Applicants had provided "considerable direction and guidance on how to practice their invention and provided working examples" and because practitioners in this art were well prepared to screen hybridomas in order to find one that made the desired antibody. 8 U.S.P.Q.2d at 1406.

In the present case, Applicants provide specific guidance that is well sufficient for one skilled in the art to make and use the invention which is an isolated antibody which is capable of binding to the Map10 protein from *Staphylococcus aureus*. In order to make and use the present invention, one needs merely to raise antibodies to Map10 and then screen the generated antibodies to determine if they bind to Map10. It is abundantly clear that such techniques are well within the capability of the ordinary practitioner in the art and will require at most routine screening using methods well known in the art. Moreover, the US Patent Office has recognized that techniques of

producing and screening antibodies are well known and routine in the art, as reflected in the Written Description Guidelines (see Appendix 1) which state:

"The level and skill in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

* * *

"Considering the **routine** art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X." (emphasis added.)

Since the US Patent Office has recognized that it is **routine** and well within the skill of the ordinary artisan to produce antibodies from a known antigen, the established criteria of the Wands case precludes a rejection on the basis of undue experimentation since where "routine" experimentation is all that is necessary, the experimentation cannot be considered "undue". Accordingly, the Examiner's rejection under 35 U.S.C. §112 on the basis of "undue experimentation" is improper and should be withdrawn.

The last remaining objection was on the basis that "acronyms such as Map10 and S. aureus" should be spelled out when first introduced in the claims. With regard to "S. aureus", Applicants have now spelled out this term in the first claim so as to obviate the rejection. However, "Map10" is not an acronym, but instead is the name the inventors gave to this protein, and this term is now accepted as the name for this protein as would be well understood by one skilled in the art. Accordingly, the use of "Map10" is proper in this case since it is not an acronym for anything else, and thus the claims using this term are entirely proper under 35 U.S.C. § 112.

In light of the amendments and arguments as set forth above, Applicants submit that the present application overcomes all prior rejections and has been placed in condition for allowance. Such action is earnestly solicited.

END OF REMARKS

Example 16: Antibodies

Specification: The specification teaches that antigen X has been isolated and is useful for detection of HIV infections. The specification teaches antigen X as purified by gel filtration and provides characterization of the antigen as having a molecular weight of 55 KD. The specification also provides a clear protocol by which antigen X was isolated. The specification contemplates but does not teach in an example antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. The general knowledge in the art is such that antibodies are structurally well characterized. It is well known that all mammals produce antibodies and they exist in five isotypes, IgM, IgG, IgD, IgA and IgE. Antibodies contain an effector portion which is the constant region and a variable region that contains the antigen binding sites in the form of complementarity determining regions and the framework regions. The sequences of constant regions as well as the variable regions subgroups (framework regions) from a variety of species are known and published in the art. It is also well known that antibodies can be made against virtually any protein.

Claim: An isolated antibody capable of binding to antigen X.

Analysis:

A review of the full content of the specification indicates that antibodies which bind to antigen X are essential to the operation of the claimed invention. The level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-

characterized antigen was conventional. This is a mature technology where the level of skill is high and advanced.

The claim is directed to any antibody which is capable of binding to antigen X.

A search of the prior art indicates that antigen X is novel and unobvious.

Considering the routine art-recognized method of making antibodies to fully characterized antigens, the well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature, one of skill in the art would have recognized that the spectrum of antibodies which bind to antigen X were implicitly disclosed as a result of the isolation of antigen X.

Conclusion: The disclosure meets the requirement under 35 USC 112 first paragraph as providing an adequate written description of the claimed invention.